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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,623	08/24/2006	Kevin J. Duffy	TC00009	2160

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SMITHKLINE BEECHAM CORPORATION
CORPORATE INTELLECTUAL PROPERTY-US, UW2220
P. O. BOX 1539
KING OF PRUSSIA, PA 19406-0939

EXAMINER

COUGHLIN, MATTHEW P

ART UNIT

PAPER NUMBER

4131

NOTIFICATION DATE

DELIVERY MODE

06/24/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary

Application No.

10/590,623

Applicant(s)

DUFFY ET AL.

Examiner

Matthew P. Coughlin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SI/02)
Paper No(s)/Mail Date 08/24/2008
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

Claims 11-22 are pending in the application.

Priority

This application is a 35 U.S.C. 371 National Stage Filing of International Application No. PCT/US05/06022, filed 02/24/2005, which claims priority under 35 U.S.C. 119(e) to Provisional Application No. 60/547543, filed 02/25/2004.

Information Disclosure Statement

The Examiner has considered the Information Disclosure Statement filed on 24 August 2006.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Applicant is reminded of the proper content of an Abstract of the Disclosure.

In chemical patent abstracts for compounds or compositions, the general nature of the compound or composition should be given as well as its use, e.g., "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." Exemplification of a species could be illustrative of members of the class. For processes, the type reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary.

The abstract of the disclosure is objected to because it neither provides for the general nature of the compound(s) nor exemplifies any members or formulae illustrative of its class. Correction is required. See MPEP § 608.01(b).

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is *undue*. These factors include, but are not limited to: (a) breadth of the claims; (b) nature of the invention; (c) state of the prior art; (d) level of one of ordinary skill in the art; (e) level of predictability in the art; (f) amount of direction provided by the inventor; (g) existence of working examples; and (h) quantity of experimentation needed to make or use the invention based on the content of the disclosure. (See *Ex parte Forman* 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988).

The above factors, regarding the present invention, are summarized as follows:

The nature of the invention

The nature of the invention involves to methods of inhibiting hYAK3 proteins in a mammal as well as treating or preventing disorder(s) that are mediated by inappropriate YAK3 activity. The correlation made in the disclosure of the instant specification is that compounds of the invention have an ability to inhibit hYAK3 kinase enzyme and such inhibition is an indicator a compound will be useful to treat or prevent a wide range of diseases if it is recognized as having hYAK3 kinase inhibiting activity.

The state of the prior art

The state of the prior art is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat or prevent which specific disease(s)). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

The predictability in the art

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In *re Fisher*, 427 F. 2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instantly claimed invention is highly unpredictable since one skilled in the art would recognize the need to screen for biological activity in regards to the therapeutic effects of all diseases, whether or not the mediation of inappropriate YAK3 activity

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would make a difference in the disease. Hence, in the absence of a showing of a nexus between any and all known diseases and the mediation of inappropriate YAK3 activity, one of ordinary skill in the art is unable to fully predict possible results from the administration of the compound of claim 1 due to the unpredictability of the role of mediation of inappropriate YAK3 activity. Those of skill in the art recognize that *in vitro* assays and or cell-cultured based assays are generally useful to observe basic physiological and cellular phenomenon such as screening the effects of potential drugs. However, clinical correlations are generally lacking. The greatly increased complexity of the *in vivo* environment as compared to the very narrowly defined and controlled conditions of an *in vitro* assay do not permit a single extrapolation of *in vitro* assays to mammalian diagnostic efficacy with any reasonable degree of predictability. *In vitro* assays cannot easily assess cell-cell interactions that may be important in a particular pathological state. Furthermore it is well known in the art that cultured cells, over a period time, lose phenotypic characteristics associated with their normal counterpart cell type. Freshney (Culture of Animal Cells, A Manual of Basic Technique, Alan R. Liss, Inc., 1983, New York, p4) teaches that it is recognized in the art that there are many differences between cultured cells and their counterparts *in vivo*. These differences stem from the dissociation of cells from a three-dimensional geometry and their propagation on a two-dimensional substrate. Specific cell interactions characteristic of histology of the tissue are lost. The culture environment lacks the input of the nervous and endocrine systems involved in homeostatic regulation *in vivo*. Without this control, cellular metabolism may be more constant *in vitro* but may not be truly representative of the tissue from which the cells were derived. This has often led to tissue

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culture being regarded in a rather skeptical light (p. 4, see Major Differences *In Vitro*). Further, although drawn specifically to cancer cells, Dermer (Bio/Technology, 1994, 12:320) teaches that, "petri dish cancer" is a poor representation of malignancy, with characteristics profoundly different from the human disease. Further, Dermer teaches that when a normal or malignant body cell adapts to immortal life in culture, it takes an evolutionary type step that enables the new line to thrive in its artificial environment. This step transforms a cell from one that is stable and differentiated to one that is not. Yet normal or malignant cells *in vivo* are not like that. The reference states that evidence of the contradictions between life on the bottom of a lab dish and in the body has been in the scientific literature for more than 30 years. Clearly it is well known in the art that cells in culture exhibit characteristics different from those *in vivo* and cannot duplicate the complex conditions of the *in vivo* environment involved in host-tumor and cell-cell interactions.

The presence or absence of working examples

Several compounds have been tested and show YAK3 activity. However, there are no working examples of what kind of condition is treatable or preventable by the mediation of inappropriate YAK3 activity.

The amount of direction or guidance present

The guidance present in the specification is lacking as to what conditions are accepted as being treatable or preventable by the mediation of inappropriate YAK3 activity. Currently, the specification teaches that many conditions appear associated with inappropriate YAK3 activity, including autoimmunity or cancer and drug-induced anemias. However further guidance is

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missing as to the connection of mediation of inappropriate YAK3 activity and the treatment or prevention of these or other conditions. The specification does not seem to enable a correlation between the mediation of inappropriate YAK3 activity and the treatment or prevention of any and all diseases.

With respect to the fact that Applicant has claimed methods of treatment or prevention of various diseases, there is no evidence of record, which would enable the skilled artisan in the identification of the people who have the potential of becoming afflicted with the numerous diseases/disorders or conditions claimed herein. That a single compound can be used to treat or prevent all diseases/disorders and conditions embraced by the claim is an incredible finding for which Applicant has not provided supporting evidence. Applicant has not provided any competent evidence or disclosed tests that are highly predictive for the pharmaceutical use for treating or preventing any or all of the diseases/disorders or conditions by administering the instant claimed compound.

The breadth of the claims

The claims are drawn to the treatment and prevention of any and all diseases mediation of inappropriate YAK3 activity with the compound of claim 2 or 3.

The quantity of experimentation needed

The quantity of experimentation needed is undue. One skilled in the art would need to determine what diseases out of all known diseases would be benefited or prevented by the mediation of inappropriate YAK3 activity and then would further need to determine which of the claimed compounds would provide treatment or prevention of the disease.

The level of the skill in the art

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Thus, the specification fails to provide sufficient support of the broad use of the compounds of claim 1 for the treatment or prevention of any disease mediated by hYAK3 activity. As a result necessitating one of ordinary skill to perform an exhaustive search for which diseases can be treated by which compound of claim 1 in order to practice the claimed invention.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, one of ordinary skill in the art would have to engage in undue experimentation to test which diseases can be treated by the compounds of the instant claims, with no assurance of success.

Claims 11-13, 17-18 and 20-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an compounds of the Formula I and/or pharmaceutically acceptable salts thereof, does not reasonably provide enablement for a solvate or hydrate of a compound of formula I. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Factors to be considered in making an enablement rejection are summarized as:

- a) the quantity of experimentation necessary,
- b) the amount of direction or guidance presented,
- c) the presence or absence of working examples,
- d) the nature of the invention,
- e) the state of the prior art,
- f) the relative skill of those in the art,
- g) the predictability or unpredictability of the art, and
- h) the breadth of the claims.

In re Colianni, 195 USPQ 150 (CCPA 1977). In re Rainer, et al., 146 USPQ 218 (CCPA 1965). Ex parte Formal, 230 USPQ 546 (BPAI 1986).

a) Determining if a particular compound would form a solvate or hydrate would require synthesis and recrystallization of the compound solvate using a variety of solvents, temperatures and humidities. The experimentation for solvates is potentially open-ended.

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b) The specification merely mentions the Applicant's intention to make solvates and hydrates, without teaching the preparation thereof.

c) While the claims recite solvates, no working examples show their formation. As stated in Morton International Inc. v. Cardinal Chemical Co., 28 USPQ2d 1190, 1194 (Fed.Cir. 1993):

The specification purports to teach, with over fifty examples, the preparation of the claimed compounds ... However ... there is no evidence that such compounds exist ... [T]he examples ... do not produce the postulated compounds ... [T]here is ... no evidence that such compounds even exist.

The specification shows no evidence of the formation and actual existence of solvates or hydrates. Hence, Applicant must show formation of solvates or limit the claims accordingly.

d) The nature of the invention is chemical synthesis of solvates and hydrates, which involves chemical reactions.

e) The state of the art recognizes that the formation, composition and therapeutic activity of solvates is unpredictable. The Federal Circuit has recognized a solvate as an example of a polymorph or pseudopolymorph (emphasis added):

"Polymorphs" are distinct crystalline structures containing the same molecules. These structural differences can affect various properties of the crystals, such as melting points and hardness (e.g., graphite and diamonds are both crystalline forms of carbon) [P]seudopolymorphs are often loosely called polymorphs ... Pseudopolymorphs not only have their molecules arranged differently but also have a slightly different molecular composition. A common type of pseudopolymorph is a solvate, which is a crystal in which the molecules defining the crystal structure "trap" molecules of a solvent. The crystal molecules and the solvent molecules then bond to form an altered crystalline structure.

SmithKline Beecham Corp. v. Apotex Corp., 74 USPQ2d 1398, 1409 (Fed.Cir.

2005). The same rationale obtains for hydrates; solvates in which the solvent is water. Souillac, et al., Characterization of Delivery Systems,

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Differential Scanning Calorimetry, pages 217-218 (in Encyclopedia of Controlled Drug Delivery, 1999, John Wiley & Sons, pages 212-227), recognize that different polymorphs of the same drug can have different therapeutic activity (emphasis added):

Because different polymorphic forms of the same drug exhibit significant differences in their physical characteristics, therapeutic activity from one form to another may be different. Studying the polymorphism of a drug and the relative stability of the different polymorphs is a critical part of pre-formulation development.

Further, Vippagunta et al. (Advanced Drug Delivery Reviews, 48 (2001), pages 3-26) state "Predicting the formation of solvates or hydrates of a compound and the number of molecules of water or solvent incorporated in to the crystal lattice of a compound is complex and difficult." See page 18, section 3.4.

f) The artisan using Applicant's disclosure to prepare the claimed solvates would be, e.g., an experienced process chemist with at least a BS chemistry degree.

g) Chemical reactions are known as unpredictable. In re Marzocchi, et al., 169 USPQ 367, 370 (CCPA 1971); In re Fisher, 166 USPQ 18, 24 (CCPA 1970). See above regarding the unpredictability of solvate and hydrate formation.

h) The breadth of the claims includes thousands of compounds of the instant formula I as well as presently unknown compounds embraced by the terms solvates. See MPEP 2164.01(a), discussed supra, justifying the conclusion of lack of enablement commensurate with the claims. Undue experimentation will be required to practice Applicant's claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-13, 15-18, and 20-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11-13, 17-18, and 20-22 are rejected because they recite the limitation of a "prodrug" where Applicant has not defined this term in the specification. From this lack of a definition, the metes and bounds of the term "prodrug" are indefinite. Prodrugs, in general, are compounds, which undergo *in vivo* conversion to parent active drugs. In that sense, recitation of prodrug is acceptable; however, the definitions of various variable groups (such as R²) include structural and functional groups, namely carbamates, and therefore the difference between these variable groups and the prodrug groups is not clear. There is clear-cut ambiguity as to what is to be considered as prodrug and what is not. Applicants should note that if the variable groups are prodrug moieties, which are in general inactive but becomes active upon *in vivo* transformation, then the compound bearing the variable group would be deemed as inactive which is not what the claim recites.

Furthermore, the issue of second paragraph is whether the structures of the claimed compounds are clearly defined. Applicants' prodrugs are molecules whose structure may lie outside the subject matter of the compounds of formula I, but upon metabolism in the body are converted to active compounds falling within the structural scope of compounds of formula I. The claim describes the function intended but provides no specific structural guidance

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to what constitutes a "prodrug". Structural formulas, names, or both can accurately describe organic compounds, which are the subject matter of claims 11-13, 17-18, and 20-22. Attempting to define means by function is not proper when the means can be clearly expressed in terms that are more precise.

Further regarding claims 11 and 12, the structural Formulae I and III have both been used to designate the same structural formula. It is suggested that Applicant amend the claims to remove the unnecessary additional label.

Claim 15 (dependent on claim 14) recites the limitation Y being a "hydrogen, halogen,...". There is insufficient antecedent basis for this limitation in the claim. It appears that "Y" should be replaced with the variable "T" in the instant claim.

Claim 15 depicts the structural limitation "T;" however, this variable is not defined in the claim. It appears that "Y" should be replaced with the variable "T" in the instant claim.

Claim 16 (dependent on claim 15) recites the limitation Q being:



. Applicant further claims that W may be N-R1 and defines R1 as -C₁₋₆ alkyl; however, claim 11 possesses a different definition for R1. It is therefore unclear which definition applies to which variable. It is suggested that Applicant label that W may be O or N-R3 so that proper antecedent basis is not lacking.

Claims 11 and 12 are rejected because they recite the limitation of "substituted" groups while Applicant has not defined the term "substituted" in the instant specification. From this language, the metes and bounds of the term "substituted" are unclear. It is suggest that Applicant clear define what substituents may be present.

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Claim 12 is rejected because it recites the limitation of R being "C₁-C₁₂aryl" or "substituted C₁-C₁₂aryl." Since the smallest non-charged aromatic ring is C₆, it is suggested that Applicant amend the variable to not include presently unknown aryl groups.

Claim Rejections - 35 USC § 103

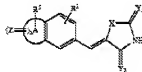
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11, 12 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. US 2005/0222225 A1 by De Luca.

Determining the scope and contents of the prior art. (See MPEP § 2141.01)

De Luca teaches compounds of the following genus for use the improvement of spermatozoa fertilization activity:



where Y₁ may be -NH. See paragraph [0104].

Ascertainment of the differences between the prior art and the claims. (See MPEP § 2141.02)

The one difference between the genus of the prior and the compounds presently claimed is that the instantly claimed compounds are generically described in the prior art when Applicant's variable "R" is hydrogen.

Finding of prima facie obviousness --- rationale and motivation (See MPEP § 2141.02)

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The indiscriminate selection of "some" among "many" is *prima facie* obvious, In re Lemin, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., as spermatozoa motility activators).

One skilled in the art at the time the invention was made would thus have been motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating, for example, infertility. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art at the time the invention was made.

Claims 11-12 and 21 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent Application Publication No. 2006/0084682 A1 by Heerding et al.

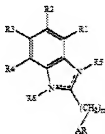
The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR

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1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(1)(1) and § 706.02(1)(2).

Determining the scope and contents of the prior art. (See MPEP § 2141.01)

Heerding et al. teach compounds of the following genus for use in the treatment of thrombocytopenia:



where R2 may be:



See claim 1 for full definition of variables.

Ascertainment of the differences between the prior art and the claims. (See MPEP § 2141.02)

The difference between the compounds of the prior art and the compounds instantly claimed is that the instant claimed compounds are generically described in the prior art. NOTE: The genus of the prior art generically

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describes the compounds instantly claimed when the presently claimed



compounds have Q = , and Z = C-aryl.

Finding of prima facie obviousness --- rationale and motivation (See MPEP § 2141.02)

The indiscriminate selection of "some" among "many" is *prima facie* obvious, *In re Lemin*, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., as TPO mimics).

One skilled in the art at the time the invention was made would thus have been motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating, for example, thrombocytopenia. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew P. Coughlin whose telephone number is (571)270-1311. The examiner can normally be reached on Monday through Thursday from 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JAMES O. WILSON can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Matthew P. Coughlin/
Examiner, Art Unit 4131

**/James O. Wilson/
Supervisory Patent Examiner, Art Unit 1624**